

REMARKS***Status of the claims***

Claims 9, 10, 13-15, and 23-39 were pending in this application. Claims 10, 13, and 14 were previously withdrawn from consideration as drawn to a non-elected invention. Applicant respectfully requests non-entry of the amendments filed in the amendment in response to the final Office Action dated September 21, 2007, which were unentered in the Advisory Action dated October 9, 2007. Claims 9 and 30 have been amended herein. Upon entry of this amendment, claims 9, 15, and 23-39 are under consideration.

The amendment to claim 30 is supported in the specification, for example, on page 9, lines 12-13 of the specification. The amendment to claim 9 is supported in the specification, for example, on page 4, lines 14-23 and page 8, line 17 – page 9, line 13. No new matter has been added by the foregoing amendments.

With respect to claim amendments and canceled claims, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Withdrawn Rejections

Applicants acknowledge with appreciation the withdrawal of rejections of claims 9, 24-27, 29, and 38 under 35 U.S.C. §102(b) and claims 15, 23, and 28 under 35 U.S.C. §103(a).

Rejections under 35 U.S.C. §102(b)

Claims 30-34, 36-39 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Banholzer et al. (1997), *Molecular and Cellular Biology* 17(6):3254-60 (“Banholzer”). The Examiner alleges that claim 30 indicates that the DNA instability sequence may be heterologous to the first DNA, the control sequence or the 3’ UTR, which is not limited to be heterologous to 3’ UTR only. Page 4 of the August 8, 2007 Office Action. As such, the teaching of Banholzer allegedly anticipates the claims. Applicants respectfully traverse this rejection.

Solely in an effort to expedite prosecution, claim 30, from which claims 31-34 and 36-39 depend, has been amended to recite “a heterologous instability sequence DNA that is heterologous to the 3’UTR sequence.” Applicants respectfully submit that Banholzer fails to anticipate the claim as amended.

As discussed in the previous response to Office Action, Banholzer discloses constructs comprising the 3’UTR of IL-3, either with or without the 3’ ARE-containing sequences. These constructs contain either the wild-type 3’UTR sequence of IL-3, or a wild-type UTR from which the native instability sequence is absent. Banholzer does not teach a construct comprising an instability sequence DNA that is heterologous to 3’UTR of the construct and thus does not anticipate the present claims which require such a heterologous instability sequence.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

Rejections under 35 U.S.C. §103(a)

Claim 35 is rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Banholzer in view of Lemm and Ross (2002) *Molecular and Cellular Biology* 22(12):3959-69 “Lemm.” Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants respectfully submit that Lemm, which was published after the priority date of the present application, would not qualify as prior art against the present application.

Furthermore, as discussed above, claim 30, from which claim 35 depends, has been amended to recite “a heterologous instability sequence DNA that is heterologous to the 3’UTR sequence.” Banholzer does not teach an expression construct comprising an instability sequence DNA that is heterologous to the 3’UTR of the construct. Lemm also does not teach or suggest such a construct. Thus, Applicants respectfully submit that Banholzer and Lemm, either alone or in combination, fail to teach or suggest all of the elements of claim 35, and as such, do not render claim 35 obvious.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Rejections under 35 U.S.C. § 112, second paragraph

Claims 9, 15, 23-29 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite due to recitation of the term “derived” in claim 9.

Solely in an effort to expedite prosecution, claim 9, from which claims 15 and 23-29 depend from, have been amended to delete the word “derived” and add the word “sequence.” The amendment makes clear that the one or more 3’ UTR sequence in the DNA expression vector and the one or more 3’UTR sequence in the control expression vector are from the same gene sequence. The rejection is thus rendered moot in view of the claim amendment.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 9, 15, and 23-29 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Examiner alleges that the limitation “wherein said one or more 3’UTR sequence in said DNA expression vector and said one or more 3’UTR sequence in said control DNA expression vector are derived from the same gene” in claim 9 lacked support in the specification. Applicants respectfully submit that support for this claim limitation can be found, for example, on page 27, lines 10-26; page 28, lines 2-8, and Example 1 of the specification. For example, page 28, lines 5-8 states,

“The control DNA expression system may be identical to the reporter gene expression system except that the DNA corresponding to the mRNA instability sequence has been removed, deleted or otherwise disabled as an mRNA instability sequence.”

The Applicants acknowledge with appreciation the Examiner’s statement in the Advisory Action dated October 09, 2007 at page 2 that the argument directed to the new matter rejection is considered persuasive.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 608352000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

Electronic Signature: /Stephanie Yonker/
Stephanie Yonker
Registration No.: 58,528
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-4227